K120494

510 (k) Summary of safety and effectiveness

JUN 1 1 2012

SUBMITTER INFORMATION

A. Company Name:	Spes Medica s.r.l.
B. Company Address:	Via Europa - Zona industriale Battipaglia (SA) – Italy 84091
C. Company Phone: Company Fax:	+ 39 0828 614191 + 39 0828 341788
D. Contact Person:	Alfredo Spadavecchia *Quality Assurance and Regulatory Affairs* Spes Medica s.r.l. e-mail: a.spadavecchia@spesmedica.com
E. Date Summary Prepared:	February 14, 2012

DEVICE IDENTIFICATION

A. Device name:	Disposable Adhesive Surface Electrodes
B. Trade/Proprietary name:	Disposable Adhesive Surface Electrodes
C. Classification name:	Cutaneous Electrode (21 CFR §882.1320)
D. Product code:	GXY

LEGALLY MARKETED DEVICES (PREDICATE DEVICES)

Predicate device	**510(k) Holder/Applicant**	**510(k) number**
RLI Cutaneous Disposable Electrode	Rhythmlink International, LLC	K052188
Bio-logic Disposable Electrode	Bio-logic Systems Corp.	K941799
Sunspots Pre-gelled Surface Electrodes	Axon System, Inc.	K062198

DEVICE DESCRIPTION

Spes Medica Disposable Adhesive Surface Electrodes are single patient use, disposable devices. Electrodes are non-invasive as they are applied to the patient's skin using a self-adhesive solid-gel surface. The electrodes consist of 3 different layers of materials.
The upper layer consists in a cotton non-woven pad, the second layer is the sensor and consists in a conductive layer. The lower layer, then the material in direct contact with the patient's skin consist in a solid Hydro-gel adhesive layer.

Spes Medica Disposable Adhesive Surface Electrodes are supplied with leads or with snap connector.

The electrodes which are attached to a lead wire terminate at the opposite end using different type of connectors such us:

- DIN 42802 "touch proof" safety connectors;
- 0,7 mm "touch proof" pin;
- Concentric "touch proof" bipolar socket;
- 2 mm "touch proof" socket;

The snap connector electrode uses Ag/AgCl pellet(s) as the conductive element. The active surface of the pellet is comprised between the cotton non-woven pad and the Hydro-gel adhesive layer. The pellet is attached to a stainless steel male snap connector which is used as connection.

INTENDED USE

Spes Medica Disposable Adhesive Surface Electrodes are intended for use with electrodiagnostic or neurological monitoring equipment for the recording of electrophysiological activity and for electrical stimulation. The electrodes are non-sterile and for single patient use only.

TECNOLOGICAL COMPARISON

Technologically, Spes Medica Disposable Adhesive Surface Electrodes are similar to the predicate devices. The electrodes are similar in intended use, design, materials, packaging and other technological characteristics to the predicate devices.
No new technology or basic materials are used in these designs.

CONCLUSION

Spes Medica Disposable Adhesive Surface Electrodes are similar in intended use, design, materials, packaging and other technological characteristics to the predicate devices. After analyzing performance and safety testing, it is the conclusion of Spes Medica s.r.l. that the Disposable Adhesive Surface Electrodes are safe and effective as the predicate devices and introduce no new questions concerning safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUN 1 1 2012

Spes Medica S.r.l.
c/o Mr. Alfredo Spadavecchia
Quality Assurance and regulatory Affairs
Via Europa, Zona Industriale
Battipaglia, Italy 84091

Re: K120494
Trade/Device Name: Disposable Adhesive Surface Electrode
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous Electrode
Regulatory Class: Class II
Product Code: GXY
Dated: May 24, 2012
Received: May 29, 2012

Dear Mr. Spadavecchia:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K120494

Device Name: Disposable Adhesive Surface Electrodes

Indications for Use:

Spes Medica Disposable Adhesive Surface Electrodes are intended for use with electrodiagnostic or neurological monitoring equipment for the recording of electrophysiological activity and for electrical stimulation. The electrodes are non-sterile and for single patient use only.

Prescription Use ___X____ (21 CFR 801 Subpart C) AND/OR Over-The-Counter Use _____ (Part 21 CFR 801 Subpart D)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

MKB Nicholas
(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K120494